Initial Approval: April 13, 2016

CRITERIA FOR PRIOR AUTHORIZATION

Strensiq® (asfotase alfa)

PROVIDER GROUP Pharmacy

MANUAL GUIDELINES The following drug requires prior authorization:
Asfotase alfa (Strensiq®)

CRITERIA FOR APPROVAL (must meet all of the following):

- Patient must have one of the following:
    a) Diagnosis of perinatal/infantile-onset hypophosphatasia (HPP)
        - Dose must not exceed 9 mg/kg/week
    b) Diagnosis of juvenile-onset hypophosphatasia (HPP)
- Patient must have a baseline ophthalmology examination and renal ultrasound

LENGTH OF APPROVAL: 6 months

CRITERIA FOR RENEWAL (must meet all of the following):

- Patient must have an ophthalmology examination and renal ultrasound at 6 months of treatment and then annually
- For a diagnosis of perinatal/infantile-onset hypophosphatasia (HPP), the dose must not exceed 9 mg/kg/week

LENGTH OF APPROVAL: 12 months

Notes:

- The recommended dosage for both indications is 6 mg/kg/week, given as either 2 mg/kg three times per weeks or 1 mg/kg six times per week.
- Three times weekly dosing at 3 mg/kg is only recommended for a diagnosis of perinatal/infantile-onset HPP, after lack of efficacy at recommended dose.
- Do not use the 80 mg/0.8 mL vial in pediatric patients weighing less than 40 kg (88 lbs) due to decreased systemic exposure than the other strength vials.